

HOUSE No. 39

Message from His Excellency the Governor recommending legislation relative to pharmacy practice in the commonwealth. January 4, 2013.

The Commonwealth of Massachusetts

EXECUTIVE DEPARTMENT

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DEVAL L. PATRICK

GOVERNOR

TIMOTHY P. MURRAY

LIEUTENANT GOVERNOR

January 4, 2013.

To the Honorable Senate and House of Representatives:

I am filing for your consideration a bill entitled, “An Act Relative to Pharmacy Practice in the Commonwealth.” This legislation builds upon recommendations made by the Commission on Compounding Pharmacies, which I formed in October 2012 as part of the Administration’s comprehensive response to the national fungal meningitis outbreak linked to products manufactured at New England Compounding Center (NECC) in Framingham. These reforms will strengthen state oversight of the compounding pharmacy industry and further protect the health and safety of patients.

This legislation will realize these goals by:

- Requiring a special license for pharmacies engaged in sterile compounding.
- Authorizing the Board of Pharmacy to assess fines against Massachusetts licensed pharmacies that violate state laws, regulations or Board of Pharmacy policies.
- Establishing whistleblower protections for pharmacists and pharmacy staff.
- Requiring licensure for out-of-state pharmacies that deliver and dispense medications in the Commonwealth.

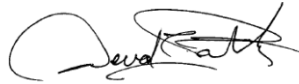
- Reorganizing the composition of the Board of Pharmacy. Under the legislation, the 11 member Board would be comprised of four pharmacists, one nurse, one physician, one pharmacy technician, one quality improvement expert, and three public members.

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DPH has already taken several steps to enhance monitoring of the compounding pharmacy industry, including advancing new, more stringent regulations. This legislation is a necessary next step toward improving the safety and quality of compounding practices in Massachusetts.

I urge your prompt and favorable consideration of this legislation.

Sincerely,

A handwritten signature in black ink, appearing to read "Deval Patrick", with a stylized flourish at the end.

DEVAL L. PATRICK,
Governor.

HOUSE No.

The Commonwealth of Massachusetts

In the Year Two Thousand Thirteen

AN ACT Relative to Pharmacy Practice in the Commonwealth.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 SECTION 1. Chapter 13 of the General Laws is hereby amended by striking out section 22 and
2 inserting in place thereof the following 2 sections:-

3 Section 22. (a) There shall be a board of registration in pharmacy, called the “board” in this
4 section and sections 23 to 25, inclusive. The governor shall appoint 11 members to the board.
5 Members shall be residents of the commonwealth. The composition of the board shall be as
6 follows: 4 registered pharmacists; 1 registered pharmacy technician; 3 representatives of the
7 public with experience in health care service delivery, administration, or consumer advocacy,
8 subject to the provisions of section 9B of this chapter; 1 physician registered pursuant to chapter
9 112; 1 nurse registered pursuant to chapter 112; and 1 expert in patient safety and quality
10 improvement;

11 (b) The 4 registered pharmacists shall each shall have had at least 7 consecutive years of
12 experience in the practice of pharmacy and shall be currently employed in the practice of
13 pharmacy in the commonwealth at the time of appointment or reappointment;

(c) At the time of appointment or reappointment to the board, at least 1 of the 4 registered pharmacist members shall be an independent pharmacist employed in the independent pharmacy setting. For the purposes of this section “independent pharmacist” shall mean a pharmacist actively engaged in the business of retail pharmacy and employed in an organization of 9 or fewer registered retail drugstores in the commonwealth under the provisions of section 39 of chapter 112 and employing not more than 20 full time pharmacists.

(d) At the time of appointment or reappointment to the board, at least 1 of the 4 registered pharmacist members shall be a chain pharmacist employed in the chain pharmacy setting. For the purposes of this section “chain pharmacist” shall mean a pharmacist in the employ of a retail drug organization operating 10 or more retail drug stores within the commonwealth under the provisions of section 39 of chapter 112.

(e) At the time of appointment or reappointment to the board, at least 1 of the 4 registered pharmacist members shall have had at least 7 years of experience as a pharmacist in a hospital setting in the commonwealth.

(f) At the time of appointment or reappointment to the board, at least 1 of the 4 registered pharmacist members shall have had at least 7 years of experience employed in a long-term care pharmacy setting.

(g) Not more than 1 pharmacist in any 1 practice setting defined in subsections (c) to (f) of this section, inclusive, may serve on the board at any one time.

(h) At the time of appointment or reappointment to the board, at least 1 of the 4 registered pharmacist members must have had at least 7 years of experience as a pharmacist engaged in sterile compounding.

(i) At the time of appointment or reappointment to the board, the pharmacy technician member shall have had at least 5 years of practical experience as a pharmacy technician and shall actually be engaged in the practice of pharmacy.

(j) For the purposes of this section, “public member” shall mean a person whose background and experience qualify her to act on the board in the public interest, including experience in health care service delivery, administration, or consumer advocacy, and who meets the provisions of section 9B(a)(4) of this chapter.

(k) Board members shall be appointed and shall serve for a term of 3 years from the first of the month following appointment. No member may serve more than 3 consecutive terms on the board. Members who have served the maximum number of consecutive terms shall be eligible for reappointment after not serving for at least one term.

(l) Any member of the board may be removed by the governor for neglect of duty, misconduct, malfeasance, or misfeasance in office. Prior to removal, such member shall be given written notice of the basis for removal and be afforded a hearing before the governor or designee. Such member may appear at the hearing with witnesses and be represented by counsel. The hearing shall be held within 21 days of the notice.

(m) Upon the death, resignation, or removal for cause of any member of the board, the governor shall fill such vacancy for the remainder of that member’s term.

SECTION 2. Section 23 of said chapter 13, as appearing in the 2010 Official Edition, is hereby amended by adding the following paragraph:-

A member may serve up to 1 year as secretary and up to 1 year as president during any single term.

SECTION 3. Section 25 of said chapter 13, as so appearing, is hereby amended by striking out, in line 1, the words “no more than six”.

SECTION 4. Section 24D of chapter 112 of the General Laws, as appearing in the 2010 Official Edition, is hereby amended by inserting after the first paragraph the following paragraph:-

The board shall participate in any national data reporting system which provides information on individual pharmacies, pharmacists and pharmacy technicians.

SECTION 5. Section 42A of said chapter 112, as so appearing, is hereby amended by inserting after the first paragraph the following paragraph:-

The board shall participate in any national data reporting system which provides information on individual pharmacies, pharmacists and pharmacy technicians.

SECTION 6. Section 39 of said chapter 112, as so appearing, is hereby amended by striking out the second sentence of the second paragraph.

SECTION 7. Section 39 of said chapter 112, as so appearing, is hereby further amended by inserting at the end thereof the following:

The board of registration in pharmacy may establish specialty pharmacy licensure categories beyond those delineated in this section, and in sections 39A-C and 39E-F of this chapter, through promulgation of regulation as deemed necessary by the board in consultation with the commissioner of public health. Said board shall determine which regulations, applicable to a retail drug business registered under section 39 shall apply to a pharmacy registered under this

section and may establish regulations which shall apply only to a licensure category established pursuant to this provision, and the fee therefore, shall be determined annually by the commissioner of administration under section 3B of chapter 7.

SECTION 8. Said chapter 112, as so appearing, is hereby further amended by inserting after section 39D the following:-

Section 39E. Sterile Compounding Pharmacy Licensure

The board of registration in pharmacy shall establish a category of pharmacy licensure for pharmacies engaged in the practice of compounding sterile medications that may present an increased potential for harm to the public. The board shall establish in regulation no later than 180 days after passage of this law, the requirements for each category of pharmacy license consistent with pertinent United States Pharmacopeia Standards and General Chapters. All pharmacies licensed pursuant to this section must hold an active license in good standing issued by the board pursuant to sections 39, 39A-C, or 39F of this chapter.

Said board shall determine which regulations, applicable to a retail drug business licensed under section 39 shall apply to a pharmacy registered under this section and may establish regulations which shall apply only to pharmacies engaged in the practice of compounding medications that may present an increased potential for harm to the public. This licensure category should include no fewer than 3 tiered permit categories determined on the basis of volume and type of medication produced. Such permits shall expire on December 31 of each year following the date of its issue, and the fee therefore, shall be determined annually by the commissioner of administration under section 3B of chapter 7.

99 SECTION 9. Said chapter 112, as so appearing, is hereby further amended by inserting after
100 section 39E the following:-

101 Section 39F. Nonresident Pharmacy Licensure

102 The board of registration in pharmacy shall establish a procedure by which to license non-
103 resident or out-of-state pharmacies, those located outside of the commonwealth selling,
104 prescribing, or dispensing medications into the commonwealth, subject to provisions of General
105 Law that pertain to the practice of pharmacy. The board may accept inspection reports or other
106 requested materials from the jurisdiction in which the pharmacy resides in its decision to approve
107 or deny a nonresident pharmacy license. The board shall establish in regulation no later than 180
108 days after passage of this law, the requirements for non-resident pharmacy licensure. A licensure
109 fee shall be determined annually by the commissioner of administration under section 3B of
110 chapter 7.

111 SECTION 10. Said chapter 112, as so appearing, is hereby further amended by inserting after
112 section 39F the following:-

113 Section 39G. Protection from Retaliation Against Employees Reporting Violations of Law or
114 Risks to Public Health, Safety, or Environment

115 (a) As used in this section, the following words shall have the following meanings:—

116 (1) “Employee”, any individual who is hired for a wage, salary, fee or payment to perform
117 services for an employer.

118

(2) “Employer”, any individual, corporation, company, association, or partnership licensed to operate a pharmacy pursuant to chapter 112 or a hospital licensed to operate a pharmacy pursuant to chapter 111, and includes officers, employees, and agents of any such corporation, company, association or partnership.

(3) “Public body”, (A) the United States Congress, any state legislature, including the general court, or any popularly elected local government body, or any member or employee thereof; (B) any federal, state or local judiciary, or any member or employee thereof, or any grand or petit jury; (C) any federal, state or local regulatory, administrative or public agency or authority, or instrumentality thereof; (D) any federal, state or local law enforcement agency, prosecutorial office, or police or peace officer; or (E) any division, board, bureau, office, committee or commission of any of the public bodies described in the above paragraphs of this subsection.

(4) “Supervisor”, any individual to whom an employer has given the authority to direct and control the work performance of the affected employee, who has authority to take corrective action regarding the violation of the law, rule or regulation of which the employee complains, or who has been designated by the employer on the notice required under subsection (g).

(5) “Retaliatory action”, the discharge, suspension or demotion of an employee, or other adverse employment action taken against an employee in the terms and conditions of employment.

(b) An employer shall not take or cause any retaliatory action against an employee because the employee does any of the following:

(1) Discloses, or threatens to disclose to a supervisor or to a public body an activity, policy or practice of the employer, or of another employer with whom the employee’s employer has a business relationship, that the employee reasonably believes is in violation of a law, or a rule or

regulation promulgated pursuant to law, or which the employee reasonably believes poses a risk to public health, safety or the environment, including but not limited to: (A) improper dispensing of prescription drugs; (B) the mishandling or misuse of raw materials; (C) unsafe, unlawful, or inappropriate sourcing of component materials; (D) unsanitary or unsafe drug preparation conditions; (E) noncompliance with state or federal reporting requirements; (F) unlawful manufacturing, (G) fraud, or (H) another matter deemed appropriate in guidance issued by the department of the attorney general;

(2) Provides information to, or testifies before, any public body conducting an investigation, hearing or inquiry into any violation of law, or a rule or regulation promulgated pursuant to law, or activity, policy or practice which the employee reasonably believes poses a risk to public health, safety or the environment by the employer, or by another employer with whom the employee's employer has a business relationship; or

(3) Objects to, or refuses to participate in any activity, policy or practice which the employee reasonably believes is in violation of a law, or a rule or regulation promulgated pursuant to law, or which the employee reasonably believes poses a risk to public health, safety or the environment.

(c) (1) Except as provided in paragraph (2), the protection against retaliatory action provided by subsection (b)(1) shall not apply to an employee who makes a disclosure to a public body unless the employee has brought the activity, policy or practice in violation of a law, or a rule or regulation promulgated pursuant to law, or which the employee reasonably believes poses a risk to public health, safety or the environment, to the attention of a supervisor of the employee by

written notice and has afforded the employer a reasonable opportunity to correct the activity,
policy or practice.

(2) Employees are not required to comply with paragraph (1) if they: (A) are reasonably certain that the activity, policy or practice is known to one or more supervisors of the employer and the situation is emergency in nature; (B) reasonably fear physical harm as a result of the disclosure provided; or (C) make the disclosure to a public body as defined in clause (B) or (D) of the definition for “public body” in subsection (a) for the purpose of providing evidence of what the employees reasonably believe to be a crime.

(d) Any employee or former employer aggrieved of a violation of this section may, within 2 years, institute a civil action in the superior court. Any party to said action shall be entitled to claim a jury trial. All remedies available in common law tort actions shall be available to prevailing plaintiffs. These remedies are in addition to any legal or equitable relief provided herein. The court may:

(1) issue temporary restraining orders or preliminary or permanent injunctions to restrain continued violation of this section;

(2) reinstate the employee to the same position held before the retaliatory action, or to an equivalent position;

(3) reinstate full fringe benefits and seniority rights to the employee;

(4) compensate the employee for 3 times the lost wages, benefits and other remuneration, and interest thereon; and

(5) order payment by the employer of reasonable costs, and attorneys’ fees.

(e) (1) Except as provided in paragraph (2), in any action brought by an employee under subsection (d), if the court finds the employee knowingly brought said action without basis in law or in fact, or the court finds that the employee acted without direction from his employer, to deliberately cause a violation posing a risk to public health, safety or the environment, the court may award reasonable attorneys' fees and court costs to the employer.

(2) An employee shall not be assessed attorneys' fees under paragraph (1) if, after exercising reasonable and diligent efforts after filing a suit, the employee moves to dismiss the action against the employer, or files a notice agreeing to a voluntary dismissal, within a reasonable time after determining that the employer would not be found liable for damages.

(f) Nothing in this section shall be deemed to diminish the rights, privileges or remedies of any employee under any other federal or state law or regulation, or under any collective bargaining agreement or employment contract; except that the institution of a private action in accordance with subsection (d) shall be deemed a waiver by the plaintiff of the rights and remedies available to him, for the actions of the employer, under any other contract, collective bargaining agreement, state law, rule or regulation, or under the common law.

(g) An employer shall conspicuously display notices reasonably designed to inform its employees of their protection and obligations under this section, and use other appropriate means to keep its employees so informed. Each notice posted pursuant to this subsection shall include the name of the person or persons the employer has designated to receive written notifications pursuant to subsection (c).

(h) All records pertaining to any complaint that falls under this section and its resolution shall be retained by the employer for five years from the date the complaint was filed and shall also be

made available to the attorney general, the department of public health, or board of pharmacy upon request of that entity. These documents shall not constitute public records subject to chapter 66 of the general laws.

SECTION 11. The first sentence of section 42A of said chapter 112, as so appearing, is hereby amended by inserting after the word “law” the following words:- or regulation.

SECTION 12. Section 42A of said chapter 112, as so appearing, is hereby amended by inserting at the end thereof the following 2 paragraphs:

The board or board president may, without holding a hearing, suspend, or refuse to renew a registrant’s license if the board or board president finds that the health, safety, or welfare of the public warrants such summary action; provided, however, that the board shall, within 7 days of such summary action, afford the registrant the opportunity of a hearing pursuant to chapter 30A. Any suspension imposed by the board or board president shall remain in effect until the conclusion of the proceedings including judicial review thereof, unless sooner dissolved by a court of competent jurisdiction or withdrawn by the board.

If, based upon evidence, the board or board president determines that a registrant or licensee or the products prepared by a registrant or licensee are an immediate threat to the public health, safety, or welfare, the board or board president may: (1) issue a cease and desist notice and/or quarantine notice requiring cessation or restriction of any and all pharmacy operations, and prohibiting the use of medications prepared by or in possession of a pharmacy; or (2) issue a cease and desist notice and/or quarantine notice placing non-disciplinary restrictions on a board registrant or licensee, to the extent necessary to avert a continued threat, pending final

investigation results. The board shall promulgate regulations pertaining to the issuance of cease and desist and quarantine notices.

SECTION 13. Said chapter 112, as so appearing, is hereby further amended by inserting after section 42A the following section:-

Section 42B. (a) The board may assess a licensed pharmacy a penalty of not more than \$25,000 for each violation of regulations or administrative rules established pursuant to any general law that governs the practice of pharmacy.

(b) The board may assess a pharmacy licensed pursuant to chapter 112, ordered to correct a violation of regulations or administrative rules established pursuant to any general law that governs the practice of pharmacy, a penalty of not more than \$1,000 for each violation for each day the violation continues to exist beyond the date prescribed for correction.

(c) Upon making an assessment, the board shall give the licensee notice of the matters alleged and the provisions of law relied upon and shall accord such person an opportunity for a hearing upon written request within 15 business days of the assessment. If after a hearing, or waiver thereof, the board determines that cause exists, the board shall make an appropriate assessment. The affected licensee shall pay such assessment except to the extent that, upon judicial review, the reviewing court may reverse the final decision of the board.

(d) An assessment made under this section shall be collected on the thirtieth day after notification to the affected licensee, or on the fifteenth day after resolution of an administrative appeal, and deposited into the Health Professions Licensure Trust. The attorney general shall recover any assessment due and payable brought in the name of the commonwealth in the

248 superior court. Funds collected under section 42B shall be paid as described in procedures
249 established pursuant to chapter 112 section 42C.

250 SECTION 14. Said chapter 112, as so appearing, is hereby further amended by inserting after
251 section 42B the following section:-

252 Section 42C. Monetary penalties collected under section 42A shall be deposited into the
253 health professions licensure trust administered by the department of public health to support
254 initiatives such as patient safety and quality improvement programs for organizations under the
255 jurisdiction of health professions licensure boards, training for board staff, and to offset the costs
256 of board business, including investigation and enforcement activities. The board shall
257 promulgate regulations for the administration of said fund, in consultation with all health
258 professions licensure boards, including the establishment of eligibility criteria, program
259 requirements, and assessment and reporting processes.

260 SECTION 15. Sections 41 and 42 of said chapter 112 are hereby repealed.

261 SECTION 16. The terms of members currently serving on the Board of Pharmacy and appointed
262 to the Board, pursuant to section 22 of chapter 112 of the general laws, prior to September 25,
263 2012 shall expire on April 30, 2013. All such members shall be eligible for reappointment.